REMARKS

With entry of the present amendment, claims 1 to 3, 6, and 9 to 12 are pending. Claims 9 to 12 are new. Claims 4 and 5 are canceled. Claims 7 and 8 were previously canceled. Claims 1 to 3 and 6 are amended. No new matter is believed to be presented by the foregoing amendments.

Claim 1 was amended to further define the claimed process as one for inhibiting the expression of human aldolase *in vitro*. The Examiner advised, in the April 4, 2007, Action, that such a process is enabled. Support for this amendment is in the application at, for example, Examples 1 to 5. Dependent claim 6 was amended to be consistent with claim 1 and dependent claims 2 and 3 were amended to clarify that the viral particles referenced therein relate back to the viral particles recited in claim 1. Support for new claims 9 to 12 is in the application at, for example, Examples 6 and 7 and in the claims as filed originally.

The addition of independent claim 9 and claims 10 to 12, which are dependent thereon and which mirror claims 2, 3, and 6, was necessitated by the fact that applicants consider such claims to be patentable over the Examiner's rejections and claim 1, as amended with the present amendment, excludes such subject matter. The reasons as to why applicants believe the claims to be patentable and thus why they should be added are discussed below. Entry of the above amendments and reconsideration of the claims, as amended and in view of the following remarks, is requested.

The Enablement Rejection

Claims 1 to 6 were rejected in the Action because the Examiner alleged that, while the specification enables a process for inhibiting human aldolase gene expression and decreasing aldolase enzyme activity in cells *in vitro* after transfection with sense and antisense viral particles, it does not reasonably provide enablement for the inhibition of expression of any target gene in cells or tissues *in vivo*.

Without conceding to the Examiner's position, applicants requested above that independent claim 1, from which claims 2, 3, and 6 depend (claims 4 and 5 have been canceled), be amended to define the process as being one for inhibiting human aldolase gene expression *in vitro*. Following such an amendment, the Examiner's enablement rejection would be overcome.

Applicants submit also that new Claims 9 to 12, which are directed to a process for inhibiting human cyclin gene expression *in vitro* are also enabled. As demonstrated in Example 6 of the present application, the claimed process does indeed successfully inhibit human cyclin gene expression *in vitro*. While Example 7 describes a process which does not result in the inhibition of human cyclin gene, Example 7 is a comparative example relating to a completely different process in which the sense RNA strand and the antisense RNA strand are contained in the same viral particle (as opposed to having the sense strand contained in a first set of viral particles and the antisense strand contained in a second set of viral particles, as required by the process of the present invention). The presently claimed process distinguishes over the prior art in that one set of viral particles contains the sense strand and another set of viral particles contains the antisense strand.

The Obviousness Rejection

Claims 1 to 6 were rejected in the pervious Action as being obvious over the combined disclosures of Heifetz et al., Fire et al., Kreutzer et al., and Lundstrom. Applicants respectfully traverse this rejection.

In the first instance, applicants submit that there does not exist a *prima facie* case of obviousness with respect to the claims as amended in view of the cited art. This is because, in order to establish a *prima facie* case of obviousness, the combined disclosures of the cited art must teach or suggest each element of the claims. In the present instance, the combined disclosures of the cited art do not teach or suggest the inhibition of human aldolase A, which is an element of claims 1 to 3 and 6 as amended. In

addition, they do not teach or suggest the inhibition of human cyclin, which is an element of new claims 9 to 12.

Further, even if the Examiner were to establish a *prima facie* case of obviousness with respect to the currently pending claims, the presence of surprising and unexpected results serves to rebut the *prima facie* case.

As submitted in the previous Reply of January 12, 2007, the practice of the present invention presents results that are surprising and unexpected over what is disclosed in the prior art. The combined disclosures of the cited art do not teach or suggest that improved results would occur if the inhibition of a target gene was obtained using a first set of viral particles consisting essentially of a sense RNA strand and a second set of viral particles consisting essentially of an anti-sense RNA strand, as required in the present invention. While Heifetz et al. suggests that the sense and antisense RNA strands may be introduced either together (for example, as double stranded RNA) or separately, it does not teach or suggest that the use of one method over the other would produce superior results. The other cited art does not teach or suggest this either. Fire et al. and Kreutzer et al. teach and suggest only the use of double stranded RNA and Lundstrom does not relate to the use of RNA in target gene inhibition at all. Thus, the combined disclosures of the cited art does not teach or suggest that introducing the sense strand and the antisense strand in different sets of viral particles would produce superior results.

By contrast, as shown in Example 6 of the present application, a process which uses a first set of viral particles consisting essentially of a sense strand of RNA and a second set of viral particles consisting essentially of an antisense strand of RNA, inhibits gene expression of human cyclin while, as shown in Example 7 of the present application, a process which involves a viral vector comprising both sense and antisense strands of RNA does not result in the inhibition of gene expression of human cyclin. As such, the use of the process of the present invention produces results that are surprising and

unexpected in view of the prior art which does not teach or suggest the superiority of using such a process.

While the Examiner has acknowledged the above argument in the final Action, she has not presented any statement as to why the aforementioned surprising and unexpected results do not rebut a *prima facie* case of obviousness.

In view of the above, applicants respectfully traverse the Examiner's obviousness rejection.

CONCLUSION

The foregoing amendment is fully responsive to the Final Office Action issued April 4, 2007. Applicants submit that the claims are allowable. Early and favorable consideration is earnestly solicited.

If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney is respectfully solicited.

Authorization to charge applicants' Deposit Account 08-2525 with respect to the Request for Continued Examination and the Petition for Extension of Time (one month) that are being filed concurrently with this Reply and Amendment has been given. Applicants believe that no further fee is due with this communication. However, should the Patent Office determine that a fee is owed, or a credit is due to applicant, the Patent Office is hereby authorized to charge any additional fees, including any extension of time and/or excess claim fees, or credit any overpayment, to applicants' Deposit Account 08-2525 as appropriate.

Respectfully submitted,

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